60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20170003A **DATE:** 23 May 2017

PROTOCOL TITLE: A Pilot Study of Open Venous Revascularization using Expandable PTFE Stent Grafts in a Porcine (*Sus scrofa*) Model.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Capt Anders Davidson

DEPARTMENT: SGSE **PHONE #:** 423-7288

INITIAL APPROVAL DATE: 17 November 2016 **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE: SG

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	3	3	3

2. **PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

___ Training: Live Animal	___ Medical Readiness	___ Prolonged Restraint
___ Training: non-Live Animal	___ Health Promotion	___ Multiple Survival Surgery
___ Research: Survival (chronic)	___ Prevention	___ Behavioral Study
_x__ Research: non-Survival (acute)	___ Utilization Mgt.	___ Adjuvant Use
___ Other ( )	___ Other (Treatment)	___ Biohazard

3. **PROTOCOL PAIN CATEGORY (USDA):** (Check applicable) ___ C _X_ D ___ E

4. **PROTOCOL STATUS:**

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

__x_ Completed, all approved procedures/animal uses have been completed

5. **Previous Amendments:**
List all amendments made to the protocol.. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
None		

6. **FUNDING STATUS:** Funding allocated: $3,518.00 Funds remaining: $0

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? ___ Yes _X_ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

N/A

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

N/A

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

No adverse events occurred during this study.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No

10. **PUBLICATIONS / PRESENTATIONS:** (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

Submitted for consideration for Presentation at Shock Society Annual Meeting 2017

Plan to submit as a letter to the editor for Journal of Trauma as an adjunct to the findings of FDG20150034A

11. **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

Yes, open revascularization with expandable PTFE stent grafts in a venous injury model is feasible and demonstrates good short term patency.

12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

Objectives: Traditional repair of traumatic venous injury typically involves open surgical repair via primary suture repair or ligation. Recent evidence from Iraq and Afghanistan has shown improved limb salvage with venous repair. However, complex venous repairs are technically challenging and time-consuming. These traits are not desirable or sometimes possible during damage control surgery or in austere environments. Emerging alternatives are expandable stent-grafts that are designed to expand within a vessel to cover an injury or open a blockage.
3 Yorkshire cross swine were anesthetized and underwent exposure of the infrarenal inferior vena cava. A 2cm near-circumferential defect was created in the vessel. A 13mm x 5cm expandable PTFE stent graft was deployed into the vessel in an open direct fashion. The swine were awoken and allowed to ambulate. At 72 hours, conduit patency was evaluated by venography. All animals appeared grossly normal with no changes on physical exam to

suggest venous insufficiency. At 72 hours, all stents were patent on venography. Direct site endovascular repair of venous injuries utilizing expandable PTFE stent grafts is a feasible technique. This technique is rapid and durable in the short term and may serve as an alternative to venous ligation during damage control surgery.

(PI / TC Signature)

24 May 2017
(Date)

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

Attachment 1
Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objectives: Traditional repair of traumatic venous injury typically involves open surgical repair via primary suture repair or ligation. Recent evidence from Iraq and Afghanistan has shown improved limb salvage with venous repair. However, complex venous repairs are technically challenging and time-consuming. These traits are not desirable or sometimes possible during damage control surgery or in austere environments. Emerging alternatives are expandable stent-grafts that are designed to expand within a vessel to cover an injury or open a blockage.

Methods: 3 Yorkshire cross swine were anesthetized and underwent exposure of the infrarenal inferior vena cava. A 2cm near-circumferential defect was created in the vessel. A 13mm x 5cm expandable PTFE stent graft was deployed into the vessel in an open direct fashion. The swine were awoken and allowed to ambulate. At 72 hours, conduit patency was evaluated by venography.

Results: All animals appeared grossly normal with no changes on physical exam to suggest venous insufficiency. At 72 hours, all stents were patent on venography.

Conclusion: Direct site endovascular repair of venous injuries utilizing expandable PTFE stent grafts is a feasible technique. This technique is rapid and durable in the short term and may serve as an alternative to venous ligation during damage control surgery.

Grant Number:_____
From:_____
****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**